REMARKS

Introduction

With entry of this amendment, claims 15-17, 22-23, and 27-32 are pending. Claims 15-17 and 30 have been amended to clarify that the pharmaceutical composition comprises a mixture of peptides obtainable by the hydrolysis of an antigenic structure. New claims 31-32 are likewise drawn to a pharmaceutical composition comprising a mixture of peptides obtained by hydrolysis of an antigenic protein. Support for the amendments can be found throughout the specification. No new matter has been added. Reconsideration is requested.

Rejection under 35 U.S.C. §102

The Examiner has rejected claims 15-17, 23, and 27-30 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Number 7,244,431 issued to Focke et al. (the '431 patent). To the extent that this rejection is considered applicable to the presently pending claims, it is respectfully traversed.

The present claims are directed to a pharmaceutical composition for sublingual, buccal or enteric administration comprising a substance comprising a mixture of peptides having a molecular weight of less than 10 kDa obtainable by hydrolysis with chymotrypsin or any other protease of an antigenic structure which induces graft rejection, allergic reaction or autoimmune disease, said antigenic structure being a protein, and said peptides being fragments of said protein.

Thus, the claimed invention comprises a mixture of peptides from the hydrolysis of allergens and not specific peptides. In contrast, the '431 patent uses a pharmaceutical composition having peptides which comprise 8 to 50 amino acids. See, e.g., the Abstract. These peptides comprise at least 3 amino acids which appear in close vicinity on the surface of the protein and are solvent exposed. *Id.* From the whole length Bet v 1 allergen, 6 specific peptides are used. See table 1. The peptides are selected by examining the structure of the target allergen and are then prepared by synthetic methods. Thus, the '431 patent contains no teaching or suggestion that a mixture of

peptides from the hydrolysis would be useful as a pharmaceutical composition, and furthermore, '431 teaches a few specific peptides that must have have specific properties in order to be effective.

In contrast, the claimed invention requires hydrolyzed fragments of allergens, i.e. the product comprises the complete hydrolyzed antigenic structure with a MW < 10,000. This can, for example, be derived from the examples of Applicant's specification. In example 1, the complete 13-lactoglobulin (BLG) is hydrolyzed and the remaining product (after removal of chymotrypsin and unhydrolyzed protein) is used. The same is true for example 2 regarding hydrolysis of insulin. Using such hydrolytic treatment does not result in a single peptide, as the hydrolysis will cleave the protein into at least two, and usually a large number of peptides of different sizes. There would be no expectation that the hydrolysis would result in any of the specific peptides disclosed by Focke et al. Accordingly, it is respectfully submitted that Focke et al. does not disclose each and every element of the claimed invention, which requires a mixture of peptide products. Reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner rejected dependent claims 28 and 29 which cover formulations designed for buccal and enteric administration, but these features are not disclosed the '431 patent. The '431 patent discloses some ways of administration including subcutaneous, intramuscular, intravenous as well as sublingual, oral or nasal administration. It does not disclose formulations for buccal or enteric administration, which are distinct from oral administration.

In rejecting claims 28 and 29, the Examiner took the position that sublingual, oral and nasal administration reads on buccal or enteric formulation under the broadest reasonable interpretation. Applicants respectfully disagree. The term "oral administration" defines only the route of administration, not the site of absorption. Typically, formulations for oral administration are tablets or the like and are dissolved in the stomach. In contrast thereto, and as described in the specification, e.g. beginning on page 5, line 15, enteric administration refers to special pharmaceutical formulations which protect the active ingredient until it enters the intestine. Thus, although Focke et al. describes oral administration, it does not disclose or render obvious a special formulation designed to protect the active compounds from absorption and/or degradation prior to

entry into the intestine. Accordingly, Applicants strongly reiterate that these are distinct formulary features for the compositions in the claims that are not disclosed in the '431 patent.

For at least these reasons, the rejection under 35 U.S.C. §102 is improper. Applicant requests that it be withdrawn.

Rejection under 35 U.S.C. §103

The Examiner has rejected claims 15-17, 22, 23, and 27-30 under 35 U.S.C. §103(a) as allegedly being obvious in view of the '431 patent and U.S. Patent Number 5,898,037 issued to Marx (the '037 patent). Applicant traverses.

The deficiencies of the '431 patent discussed above are not remedied by the '037 patent, which deals with formulations of magnesium compounds for local administration. The claims require a mixture of peptides from the hydrolysis of allergens and this feature is not shown or suggested in the cited references, even if combined. Moreover, the routes of administration of claims 28 and 29 for the claimed formulation are not shown or fairly suggested in the cited references.

For at least these reasons, the rejection under 35 U.S.C. §103(a) is improper because the combination fails to teach each and every element of the claims. Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of the claims and that the application be passed to issue. If the Examiner believes, for any reason, that personal

communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Dated: June 18, 2010

Respectfully submitted,

By:/Ann S. Hobbs/ 36,830
Ann S. Hobbs
Registration No. 36,830:
VENABLE LLP
P.O. Box 34385
Washington, DC 20043-9998
(202) 344-4000
(202) 344-8300 (Fax)
Attorney/Agent For Applicant